

# Public Interest in Medical Research Participation: Does It Matter if Patients or Community Members Have Helped Design the Study?

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## Abstract

**Purpose:** We determined national levels of public participation in medical research study design. We compared public interest in medical research participation (MRP) in studies overall, versus studies explicitly designed with public involvement.

**Method:** Cross-sectional household survey of US population in June 2013. Descriptive statistics estimated participation in medical research study design. Chi-square test compared levels of interest in MRP if respondent knew patients or community members helped design the study.

**Results:** Of 2,048 respondents (participation rate 60%), 5% knew someone who had helped design a medical research study. There was no association between having known someone or personal participation in study design and willingness to engage in MRP. Although the overall proportion of respondents who would consider MRP initially (51%) was similar to the proportion who would consider MRP with community member involvement in study design (49%), the changes in respondents' views across the different scenarios were significantly greater than what would have been expected by chance.

**Conclusions:** We found similar levels of interest in MRP whether or not the public is involved in medical research study design. This finding may indicate that public involvement in study design, like community-based participatory research, may not affect overall rates of MRP. *Clin Trans Sci* 2015; Volume 8: 502–505

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## Background

In the United States, clinical trials are frequently limited by low rates of participation by the public.<sup>1</sup> In a recent sample of over 900 trials registered at Clinicaltrials.gov, approximately 39% were terminated due to lack of participation.<sup>2</sup> As a result, many studies do not meet enrollment goals, cost more than expected, and fail to inform clinical practice guidelines.<sup>3</sup> Without the critical knowledge gained from medical research, clinical medicine is less likely to evolve, advance treatments, and ultimately cure disease.

One response to the challenges of poor medical research participation (MRP) by the public has been to employ approaches that are more “community-engaged” and “patient-centered.”<sup>4</sup> This approach has specifically been used to address low recruitment and disparities in MRP by racial/ethnic minorities. Agencies such as the Patient Centered Outcomes Research Institute (PCORI) have generated further impetus for the movement by funding research that must include a component of patient engagement.<sup>5</sup>

However, it is unclear whether engaging patients, patient advocates, and/or community members in clinical trial design will improve MRP rates. In this study of a nationally representative sample of the US population, we survey the public's interest in MRP, knowledge of someone who has helped design medical research, and whether awareness of patient or community member involvement in study design influences public interest in participation. The first objective of this study was to determine the public's interest in MRP if the study is “patient-centered” by having a patient or community member involved in the study design. A second objective was to determine factors associated with interest in MRP if the study is “patient-centered.”

## Methods

### Study sample

In June 2013, the authors collaborated with GfK to field this Web-based survey of the US population. The survey was cross-sectional and used the national Web-enabled KnowledgePanel recruited and maintained by GfK that includes landline and cellphone only households<sup>6</sup> using a 50-state sampling technique. This online research platform has been the basis for a number of peer-reviewed publications focused on measurement of nationally representative perceptions and behavioral intentions related to health and research.<sup>1,7-11</sup> To assure that households from a broad distribution of income strata, age groups, and racial/ethnic groups are included in the study, GfK/Knowledge Networks uses probability-based sampling of US Postal Service delivery addresses and supplies internet access for interested participants without computer hardware or internet access. Upon survey completion, respondents were given points toward cash, gift cards, or merchandise by GfK; this compensation was managed by GfK rather than the authors and was commensurate with compensation provided for responding to other surveys to which they were invited.

We asked survey respondents about their interest in MRP as volunteers exposed to low risks if they had the disease being studied (hereafter referred to as “diagnosed volunteers”). We inquired about their interest in MRP if a patient or community member helped design the study. Survey respondents provided sociodemographic information including gender, age, health insurance status, employment status, race/ethnicity, and annual household income.

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For statistical analyses described below, survey responses with categories were collapsed from “yes,” “no,” or “unsure” to “yes” versus “no.”

### Statistical analyses

We used descriptive statistics to estimate the proportions of study participants who would consider MRP as diagnosed volunteers, and also as diagnosed volunteers in a study in which a patient or community member was involved in study design. We used chi-squared tests to examine differences in interest in MRP related to studies in general versus studies designed with community members.

We then used multivariable logistic regression to examine whether sociodemographic factors (gender, age, education, health insurance status, employment status, race/ethnicity, and annual household income) were associated with interest in MRP for studies in general, versus studies designed explicitly with community member input.

Sampling weights supplied by GfK were included in all analyses to permit nationally representative inferences using Stata, version 12 (Stata Corporation; College Station, TX, USA).

### Results

A total of 2,078 adults participated in this study (participation rate 60%). *Table 1* presents characteristics of the study sample.

#### Interest in MRP related to community member involvement in study design

Overall, about one-half of respondents (51%) said that they would consider MRP as diagnosed volunteers if the study risks were described as low.

Only 5% of respondents had themselves helped design or knew a layperson who had helped design a medical study previously. Respondents were asked to imagine that they were asked to participate in a study in which patients like themselves or members of their community had been involved in the study design. Again, about one-half of respondents (49%) stated that they would consider MRP in this type of low-risk research as diagnosed volunteers.

Of note, 14% of study participants who initially responded that they would not consider MRP subsequently said that they would consider MRP if a patient or community member helped design the study. Meanwhile, 18% of study participants who initially said that they would consider MRP subsequently said that they would not consider MRP if a patient or community member helped design the study (*Table 2*). Although the overall proportion of respondents who would consider MRP initially (51%) was very similar to MRP with involvement of a community member in study design (49%), the changes in respondents' views across the different scenarios were significantly greater than what would have been expected by chance ( $p < 0.001$ ).

In multivariable logistic regression models, several sociodemographic factors were associated with MRP consideration (*Table 3*). When considering MRP as diagnosed volunteers, survey respondents with at least bachelor's degrees were significantly more likely than those with only high school education to say they would consider MRP. When considering MRP in a study that a patient or community member helped design, female gender and non-Hispanic black race were associated with lower odds of considering MRP, compared to males and non-Hispanic whites, respectively (*Table 3*). In addition, survey respondents with at

Age of respondents (years)	
18–29	21%
30–44	26%
45–59	28%
60+	26%
Gender	
Male	49%
Female	51%
Race/ethnicity	
White, non-Hispanic	68%
Black, non-Hispanic	11%
Hispanic	14%
Other, non-Hispanic	7%
Education	
Less than high school	12%
High school	30%
Some college	28%
Bachelor's degree+	30%
Annual household income	
Up to \$29,999	23%
\$30,000–\$59,999	27%
\$60,000–\$99,999	24%
\$100,000 or more	26%
Health Insurance at time of survey completion	
Private	65%
Public	23%
None	12%
Employment status at time of survey completion	
Working	59%
Not working—retired	17%
Not working—disabled	6%
Not working—other	18%

\*Proportions within individual variable may not sum to 100% because of rounding.

**Table 1.** Characteristics of study respondents ( $n = 2,078$ )\*

Would consider MRP as diagnosed Volunteer	Would Consider MRP if a Patient or Community Member Helped Design the Study	
	No	Yes
No	86%	14%
Yes	18%	82%

**Table 2.** Proportions of respondents who would consider medical research participation (MRP) as diagnosed volunteers and if they knew a patient or community member helped design the study.

least bachelor's degrees and those who reported being disabled were more likely to consider MRP with community member input compared to survey respondents with only high school education and who were employed, respectively.

	Medical research participation as diagnosed volunteer if low risk adjusted* odds ratio (95% CI)	MRP if patient or community member involved in study design adjusted* odds ratio (95% CI)
<b>Age (years)</b>		
18–29	1.0 (ref)	1.0 (ref)
30–44	0.91 (0.57–1.45)	0.88 (0.56–1.40)
45–59	1.30 (0.79–2.13)	1.10 (0.67–1.81)
≥60	0.84 (0.45–1.58)	0.83 (0.43–1.59)
<b>Gender</b>		
Male	1.0 (ref)	1.0 (ref)
Female	0.85 (0.62–1.16)	<b>0.65</b> (0.48–0.89)
<b>Race/Ethnicity</b>		
White, non-Hispanic	1.0 (ref)	1.0 (ref)
Black, non-Hispanic	0.64 (0.40–1.05)	<b>0.54</b> (0.32–0.90)
Hispanic	0.79 (0.46–1.33)	0.83 (0.50–1.37)
Other, non-Hispanic	0.73 (0.36–1.46)	0.75 (0.37–1.50)
<b>Education</b>		
Less than high school	0.71 (0.40–1.28)	0.98 (0.54–1.78)
High school	1.0 (ref)	1.0 (ref)
Some college	1.21 (0.80–1.82)	1.27 (0.84–1.91)
Bachelor's degree or higher	<b>1.90</b> (1.25–2.90)	<b>1.84</b> (1.20–2.82)
<b>Annual household income</b>		
Up to \$29,999	1.0 (ref)	1.0 (ref)
\$30,000–\$59,999	1.05 (0.66–1.67)	1.20 (0.74–1.95)
\$60,000–\$99,999	1.35 (0.82–2.21)	1.45 (0.87–2.41)
\$100,000 or more	1.17 (0.71–1.94)	1.59 (0.94–2.66)
<b>Health insurance at time of survey completion</b>		
Private	1.0 (ref)	1.0 (ref)
Public	0.79 (0.51–1.23)	1.05 (0.68–1.63)
None	0.63 (0.38–1.03)	0.89 (0.53–1.48)
<b>Employment status at time of survey completion</b>		
Working	1.0 (ref)	1.0 (ref)
Not working—retired	1.09 (0.59–2.00)	0.97 (0.51–1.85)
Not working—disabled	2.08 (0.90–4.83)	<b>2.24</b> (1.05–4.77)
Not working—other	1.29 (0.84–1.99)	1.19 (0.77–1.83)

\*Adjusted for all the other variables listed in the table. Bold values indicate statistical significance.

**Table 3.** Adjusted odds of consideration of medical research participation if a patient or community member helped design the study.

Having participated personally in study design as a patient or community member, or knowing someone who had, was not associated with willingness to participate in MRP as a diagnosed volunteer.

## Discussion

To our knowledge, this is the first study to examine rates of US public interest in MRP when a patient or community member is involved in study design. Our main finding is that about one-half

of respondents in this nationally representative sample of the US population are interested in MRP as diagnosed volunteers, whether or not the study is described as including a patient or community member in its design.

Comparing these proportions, it seems that patient-engaged research design such as that supported by PCORI or produced through community-based participatory research (CBPR) may not influence the public to participate in medical research at higher rates. However, the overall similarity in proportions of respondents who would consider MRP obscures key facets of findings from this study about adults' consideration of MRP when patients or community members are involved in study design. One out of seven adults who said they would not consider MRP as a diagnosed volunteer in general indicated that they would consider MRP when a patient or community member were involved in study design. For this subgroup of respondents, inclusion of community members in study design appears to have been a particularly compelling feature of the opportunity to contribute to medical research. Our analysis suggests that sociodemographic factors such as disability, higher educational attainment, male gender, and non-Hispanic white race were associated with willingness to participate in studies designed in part by community members and patients.

On the other hand, a similar share of adults who had expressed a willingness to consider participating originally were not willing to do so when a community member was involved in study design. To maximize MRP when study design is informed by community input,

it will be helpful to understand what attitudes and perceptions about such involvement are discouraging potential subjects from participating. We found that some respondents, specifically females and non-Hispanic blacks, were less likely to consider MRP if a patient or community member helped with study design. In contrast, De Las Nueces et al. found that using CBPR led to successful recruitment and retention of minority participants.<sup>12</sup> However, this difference may be attributed to the fact that our survey asked only about the involvement of a patient or

community member in the design of the study, and not specifically in other aspects of medical research that may be important to this group such as subject recruitment, intervention delivery, and data collection.

Overall, we found that 51% of the respondents were interested in MRP as diagnosed volunteers in studies described as low risk. This proportion is about 10% lower than that reported by Cobb et al. from data collected in 2012.<sup>7</sup> Nonetheless, if one-half of community-dwelling adults would consider participating in medical research, then that suggests that there is a large national pool of potential subjects. Further, it suggests that there is still work to do to translate willingness to participate into actual study participation.

This study illuminates the opportunities and challenges of research participation in novel ways but also has limitations. We used a cross-sectional survey design and therefore cannot determine causal relationships. Furthermore, survey participants were asked about hypothetical scenarios, and therefore their responses may differ once invited to participate in medical research.

### Conclusion

In this study of general population attitudes about MRP, we found high levels of interest in MRP that were sustained—though not enhanced—when a study was designed in partnership with a patient or community member. Levels of public involvement or knowledge of someone involved in medical research study design are low and may indicate a need to increase awareness of opportunities for patient involvement in clinical trial design.

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